DATA EVALUATION RECORD 5

CHEM 129171 AC 299,263 §162-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 43876231
Cady, C. June 1995. AC 299,263: Biotransformation of ^{14}C-299,263 Under Anaerobic Aquatic Conditions. Laboratory Project No. ENV 95-25. Unpublished study performed by ABC Laboratories, Inc., Columbia, MO, and submitted by American Cyanamid Company, Princeton, NJ.

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CONCLUSIONS:

Metabolism - Anaerobic Aquatic

1. The anaerobic aquatic metabolism study is acceptable and satisfies the 162-3 data requirement for AC 299,263.

2. ^{14}C-AC 299,263 did not degrade significantly in anaerobic aquatic sandy loam sediment/water systems incubated for up to 365 days. The treatments were 4 °C (non-sterile), 25 °C (non-sterile), and 25 °C (sterile). The calculated, extrapolated half-lives were undefined (no degradation), 761 days, and 1439 days, respectively.

3. Aqueous residues were 32-52 % of total radioactivity in the study. Volatile residues did not exceed 0.2 % of applied in any of the treatments. Fulvic acid (extractable) residues generally increased from 36-43 to 51-63 % by the end of the study. The degradate AC 336,554 (parent compound with a broken ring with two amide groups) reached significant levels in the 25 °C, non-sterile treatment, but did not reach significant levels in the other treatments. Mean total recoveries ranged from 94-109 % of applied in no particular pattern.


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METHODOLOGY:

Pyridine C-6 labeled [^{14}C]AC 299,263 (2-(4-isopropyl-4-methyl-5-oxo-2-imiodazolin-2-yl)-5-methoxymethyl nicotinic acid; radiochemical purity 99.4 %, specific activity 88 uCi/mg, American Cyanamid, dissolved in millipore water, was made into solutions where 20 ul contained 1.75 ug of AC 299,263. The 20 ul of treatment solution were applied to a sediment:water system in an aeration vessel containg 50 g (oven-dry basis) and 75 ml of pond water (See Comments 1 and 2 for sediment and water characteristics, respectively).

The vessels were connected to an air-flow system complete with moistened nitrogen gas and volatility traps for organics and CO_2. For the 25 °C non-sterile and sterile systems, samples were collected for analysis at 0, 7, 14, and 21 days, and 1, 2, 3, 4, 6, 9, and 12 months after treatment. For the 4 °C treatment, the vessels were collected for analysis at 14, 28, and 40 days, and at 2, 3, 4, 6, 9, and 12 months. Volatility traps were removed and sampled at each interval for each treatment, with replacement solutions installed immediately.

The samples were centrifuged at 2500 rpm (1000 g) for 10 minutes, and the water was decanted into graduated cylinders where the volume was recorded. The sediment was extracted 3 times with 0.1 M EDTA and 3 times with 0.5 N NaOH, followed by determination of soil-bound residues by oxidative combustion analysis.

The aqueous portions of the samples and soil extracts were analyzed using radioassay, TLC, and HPLC. Prior to final analysis, the samples or extracts were stored for up to 14 days. For more details about the methodology, see the attached Materials and Methods from the study.

Data Summary:

^{14}C-AC 299,263 did not degrade significantly in anaerobic aquatic sandy loam sediment/water systems incubated for up to 365 days. The treatments were 4 °C (non-sterile), 25 °C (non-sterile), and 25 °C (sterile). The calculated, extrapolated half-lives were undefined (no degradation), 761 days, and 1439 days, respectively.

Aqueous residues were 32-52 % of total radioactivity in the study. Volatile residues did not exceed 0.2 % of applied in any of the treatments. In the non-sterile treatments, fulvic acid (extractable) residues generally increased from 36 to 51-54 % by the end of the study. In the sterile system, fulvic acid residues increased from 43 % at zero days after treatment to 63 % by the end of the study. Mean total recoveries ranged from 94-109 % of applied in no particular pattern.

The degradate AC 336,554 (parent compound with a broken ring with two amide groups) reached significant levels in the 25 °C, non-sterile treatment, but did not reach significant levels in the other treatments. The structure and scientific names of the parent and metabolites may be seen in the attached p. 15 of the study. The Limit of Quantition (LOQ)

for both sediment and water was 0.5 ppb, representing <1.4 % of the applied dose.

COMMENTS:

1. Sediment Properties

Property	Sediment
Particle Size Distribution	sandy loam*
Sand (%)	74
Silt (%)	14
Clay (%)	12
Organic Carbon	2.1 (OM)
pH (1 M $CaCl_2$)	7.7
% Field moisture at 1/3 bar	12.8
Cation Exchange (CEC, meq/100g)	22.9

* Analysis performed by Harris Laboratories, Lincoln, NE.

2. Pond Water Properties

Dissolved Oxygen (mg/L)	8.8
Alkalinity (mg/L)	109
pH	8.1
Conductivity (umhos/cm)	280

3. It was not clear if, prior to extraction, the pH of the water and the Eh of the soil were measured in all the samples.